

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

LINDA S. BOBLETZ,

Plaintiff,

**ANSWER OF KSEA
TO FIRST AMENDED
COMPLAINT**

vs.

Civil Action No. 3:14-cv-1024 (TJM/DEP)

KARL STORZ ENDOSCOPY-AMERICA, INC.,
KARL STORZ ENDOVISION, INC., KARL
STORZ GMBH & CO. KG, and ABC
CORPORATIONS 1-10 and JOHN ODES
1-10 and JANE DOES 1-10,

Defendants.

KARL STORZ ENDOSCOPY-AMERICA, INC., (hereinafter "KSEA") by its attorneys,
Goldberg Segalla LLP for its Answer to Plaintiff's Amended Complaint, states as follows:

FIRST. Denies knowledge of information sufficient to form a belief with respect to the
allegations of paragraph "1" of the Amended Complaint.

SECOND. Denies knowledge or information sufficient to form a belief with respect to the
allegations of paragraph "2" of the Amended Complaint.

THIRD. Denies knowledge or information sufficient to form a belief with respect to the
allegations of paragraph "3" of the Amended Complaint.

FOURTH. Denies knowledge or information sufficient to form a belief with respect to the
allegations of paragraph "4" of the Amended Complaint.

FIFTH. Answering paragraph "5" of the Amended Complaint, defendant admits that KSEA is incorporated in California, that it has its principal place of business in El Segundo, California, that it distributes morcellators in the United States. The remaining allegations in paragraph "5" call for a legal conclusion to which no response is required. To the extent a response is required, the remaining allegations contained in that paragraph are denied.

SIXTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "6" of the Amended Complaint.

SEVENTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "7" of the Amended Complaint.

EIGHTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "8" of the Amended Complaint.

NINTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "9" of the Amended Complaint.

TENTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "10" of the Amended Complaint.

ELEVENTH. Denies knowledge or information sufficient to form a belief with respect to the allegations of paragraph "11" of the Amended Complaint.

COUNT I – NEGLIGENCE

TWELFTH. With respect to the allegations of paragraph "12" of the Amended Complaint, admits those allegations as are elsewhere admitted, denies those allegations as are elsewhere herein denied, and denies knowledge or information sufficient to form a belief as to those allegations as are elsewhere herein similarly treated.

THIRTEENTH. KSEA states that the allegations contained in paragraph "13" of the Amended Complaint constitute conclusions of law to which no response is required. KSEA denies the remaining allegations contained in paragraph "13" of the Amended Complaint to the extent that they do not constitute conclusions of law.

FOURTEENTH. KSEA states that the allegations contained in paragraph "14" of the Amended Complaint constitute conclusions of law to which no response is required. KSEA denies the remaining allegations contained in paragraph "13" of the Amended Complaint to the extent that they do not constitute conclusions of law.

FIFTEENTH. Denies the allegations contained in paragraph "15" of the Amended Complaint.

SIXTEENTH. Denies the allegations contained in paragraph "16" of the Amended Complaint.

COUNT II – STRICT PRODUCTS LIABILITY

SEVENTEENTH. With respect to the allegations of paragraph "17" of the Amended Complaint, KSEA admits those allegations as are elsewhere admitted, denies those allegations as are elsewhere herein denied, and denies knowledge or information sufficient to form a belief as to those allegations as are elsewhere herein similarly treated.

EIGHTEENTH. Denies the allegations contained in paragraph "18" of the Amended Complaint.

NINETEENTH. Denies the allegations contained in paragraph "19" of the Amended Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

At all times relevant to the instant matter, defendant KSEA was the exclusive importer and distributor (but not the designer nor manufacturer) of the subject product that KSEA allegedly supplied to the referenced medical facility, which was subsequently and purportedly used in the care, treatment and/or surgery of Plaintiff.

SECOND AFFIRMATIVE DEFENSE

That one or more of the causes of action in the Complaint fail to state a cause of action upon which relief may be granted.

THIRD AFFIRMATIVE DEFENSE

The Complaint is insufficiently pleaded under *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007).

FOURTH AFFIRMATIVE DEFENSE

KSEA affirmatively pleads the application of the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto. Adequate warnings and complete warnings were provided to Plaintiff's physician, and therefore, the product was not defective or unreasonably dangerous.

FIFTH AFFIRMATIVE DEFENSE

KSEA is entitled to, and claims the benefits of, all defenses and presumptions set forth in or arising from any rule of law or statute in the state of New York, Plaintiff's alleged state of citizenship and residence, and any other state whose law is deemed to apply in this case.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because her injuries, if any, were caused in whole or in part by something over which or someone over whom KSEA had no control.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's injuries and damages, if any, were caused exclusively by the intervening superseding negligence of others.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's failure to warn claim is barred by the learned intermediary doctrine.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by Plaintiff's pre-existing condition.

TENTH AFFIRMATIVE DEFENSE

Upon information and believe, any product that KSEA allegedly supplied to the referenced medical facility (which was subsequently and allegedly used in a medical procedure on the Plaintiff) met and was in conformity with the generally recognized, reasonably available and reliable state of the art and the prevailing standards of the medical industry at the time of the manufacture and/or distribution. Accordingly, and upon information and belief and on the state of the scientific, medical and technical knowledge at the time the subject product was supplied, the subject product was reasonably safe for its normal and foreseeable use at all relevant times.

ELEVENTH AFFIRMATIVE DEFENSE

The subject product at issue was not defective in design or manufacture and the warnings and instructions for the subject product at issue were presumptively adequate.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because the utility of the Rotocut G1 morcellator outweighs any risks, if any.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's recovery, if any, should be diminished in proportion to any culpable conduct in accordance with N.Y. C.P.L.R. § 1411.

FOURTEENTH AFFIRMATIVE DEFENSE

If KSEA is found liable to Plaintiff for any non-economic loss allegedly suffered, which is denied, such liability equals fifty percent or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds fifty percent of the total liability. Therefore, pursuant to N.Y. C.P.L.R. Article 16, KSEA's liability, if any, to Plaintiff for her non-economic loss shall not exceed KSEA's equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claim for the cost of medical expenses and other economic loss is subject to the provisions of N.Y. C.P.L.R. § 4545 and any such past or future costs or expenses which were or will be replaced or indemnified, in whole or in part, from any collateral source are not recoverable in this action.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff's claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

SEVENTEENTH AFFIRMATIVE DEFENSE

KSEA hereby gives notice that it intends to rely on such other affirmative defenses as may become available or apparent during the course of discovery and reserves the right to amend its Answer to assert any such defense.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that the Complaint herein and the claims made by Plaintiff were not commenced within the time limited by law, the Complaint is barred by the statute of limitations.

NINETEENTH AFFIRMATIVE DEFENSE

That Plaintiff has failed to mitigate her damages.

TWENTIETH AFFIRMATIVE DEFENSE

If the Plaintiff sustained the injuries and damages alleged, then said injuries and damages were proximately caused by persons and/or entities not connected with the defendant, and for whom defendant bears no legal responsibility.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The subject product was supplied to and used by "sophisticated users," who either knew or should have known of the nature of the products alleged to have been used with respect to Plaintiff.

TWENTY-SECOND AFFIRMATIVE DEFENSE

That the subject product at issue is not defective because a reasonable health care provider, knowing of the foreseeable risks and therapeutic benefits of the product, would use the product in treatment of patients.

TWENTY-THIRD AFFIRMATIVE DEFENSE

That Plaintiff's alleged injuries, if any, were not the result of any act or omission on the part

of KSEA, but exist by reason of operation of nature or idiosyncratic or allergic reaction over which KSEA had no control.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

That the subject product is not unreasonably dangerous.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

That the Complaint fails to allege sufficient facts to fully apprise defendant of the nature of the claims.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

That, upon information and belief, at all times relevant herein, product warnings, instructions and labeling were adequate and in compliance with all applicable Federal, State and industry ordinances, regulations and guidelines.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

That Plaintiff's claims are barred by federal preemption.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Upon information and belief, Plaintiff's claims are preempted in whole or in part under the supremacy clause of the Constitution of the United States, because the subject product had been approved and/or cleared by the FDA and, upon information and belief, had been tested, manufactured, and labeled in accordance with FDA requirements, pursuant to 21 U.S.C. § 301, et seq.

TWENTY-NINTH AFFIRMATIVE DEFENSE

That the subject product at issue was merchantable and reasonably suited to the use intended and its condition when supplied and was not the proximate cause of any alleged injury to the

Plaintiff.

THIRTIETH AFFIRMATIVE DEFENSE

That Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver and/or estoppel.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendant contends that there is no basis for liability in regards to its acts and/or conduct relevant herein. However, without withdrawing or compromising that position, defendant alleges, in the alternative, that should it be found liable to the Plaintiff, in some manner or to some extent, defendant is entitled to contribution and/or indemnification and/or a set off as to all responsible persons and/or by those entities who would be otherwise liable to Plaintiff, if joined herein, according to the degree of involvement or responsibility for any such loss and/or damages to the Plaintiff.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to the subject product that KSEA allegedly supplied to the referenced medical facility (which were subsequently used in the care, treatment and/or surgery of Plaintiff), the Plaintiff's recovery is barred since, at the time the alleged subject product was manufactured, there was (were) no other practicable and/or feasible alternative design(s) which would have prevented the injuries and damages allegedly sustained by the Plaintiffs without substantially impairing the usefulness, efficacy and/or intended function of such alleged subject product.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Any and all events and incidents, relevant to the instant matter, as well as any alleged injuries and/or damages of the Plaintiff were proximately caused and/or otherwise contributed to by Plaintiff

in that Plaintiff voluntarily and knowingly consented to the surgical procedure and medical treatments on Plaintiff and, thus, voluntarily and knowingly assumed all the medical risks and hazards, as well as all possible adverse effects and consequences pertaining to, connected with, or otherwise related to the subject medical procedure and said Plaintiff's related care and treatment, after being fully advised of such risks, by individuals and/or parties other than KSEA.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims against Defendant KSEA are barred to the extent that the subject product at issue was misused, improperly used, erected, etc.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

The action cannot proceed in the absence of all other parties who should be named in accordance with CPLR Section 1001.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

The causes of action, if any, are barred by the assumption of the risk.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, KSEA demands a trial by jury, composed of the maximum number of jurors allowed by law, on all of the issues so triable as of right.

WHEREFORE, judgment is demanded as follows:

1. Dismissing the Complaint against KSEA;
2. Diminishing the damages otherwise recoverable pursuant to Article 14-A of the CPLR;
3. Limiting liability for non-economic loss pursuant to Article 16 of the CPLR;
4. For the costs, disbursements and attorney's fees of this action; and
5. For such other, further and different relief which may seem just, proper and equitable.

DATED: February 2, 2015
Syracuse, New York

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